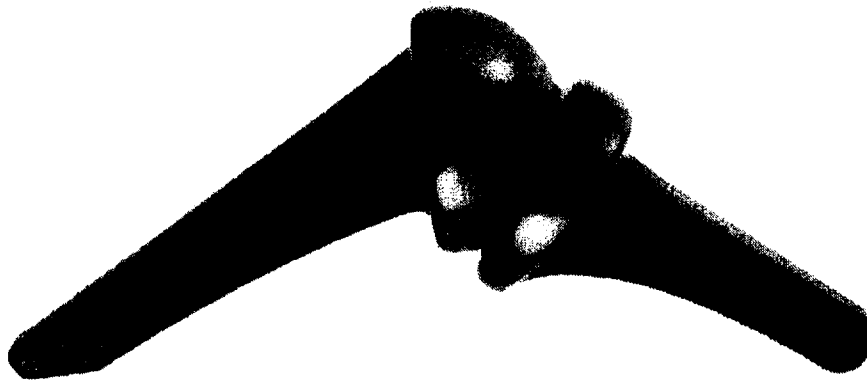


## **Proposed Patient Labeling**

### **1. WHAT IS THE ASCENSION® MCP?**

The Ascension® MCP is a two-piece joint implant. Each piece is made of a special form of carbon called "pyrocarbon." It is used to replace the knuckle joint where your finger connects to your hand. It should reduce your pain and help your finger move. The Ascension MCP is easy to see on x-rays.



**The Ascension® MCP**



**X-ray of the Ascension® MCP**

## **2. WHEN IS THE ASCENSION® MCP USED?**

If you are reading this brochure, your doctor has probably said the Ascension MCP implant is the best treatment for you. It is used when your knuckle joint is painful, stiff, or cannot move because of arthritis or injury.

## **3. WHEN SHOULD THE ASCENSION® MCP NOT BE USED?**

The Ascension MCP should not be used if you have:

- thin or weak bones or other bone problems
- an infection in the joint
- finger or hand muscles or tendons that do not work and cannot be repaired
- other hand or wrist implants that block insertion or motion of the Ascension MCP
- problems with cuts healing or other skin problems
- problems with numbness or tingling in your hands or fingers

#### **4. WHAT ARE THE RISKS AND BENEFITS?**

There are many potential benefits with the Ascension MCP. It may:

- reduce finger joint pain
- help your finger move
- improve how your hand looks

Keep in mind that your medical condition may limit your improvements. The Ascension MCP should not cause you any harm or pain. But complications can occur and may reduce the success of the surgery.

You should call the doctor if your finger becomes:

- red
- hot
- swollen
- painful, or
- you develop a fever

Heavy loads on your hand or fingers may cause problems, such as implant loosening, fracture, or wear. If you have any of these problems, call your doctor:

- sudden onset of pain
- sudden change in joint function or motion
- a bent, crooked or twisted finger

Finger surgery may also cause some problems. These problems do not usually happen, but it is best to know the risks. Finger surgery may result in:

- a longer or shorter finger
- pain when your finger moves or when it is still
- pain at night or when the weather changes
- finger joint stiffness
- less or no finger motion
- a dislocated joint
- a bent, crooked or twisted finger
- a useless finger or hand (permanent disability)
- a joint that is fused or a different implant because, due to a variety of factors, the Ascension MCP cannot be implanted
- more surgery to fix a bent or twisted finger or dislocated joint
- more surgery to remove the implant or fuse the joint
- bleeding, infection, or numbness (nerve damage)
- damage to blood vessels or tendons or tissue around the joint
- finger amputation
- death

## 5. EXPECTATIONS OF SURGERY AND THERAPY

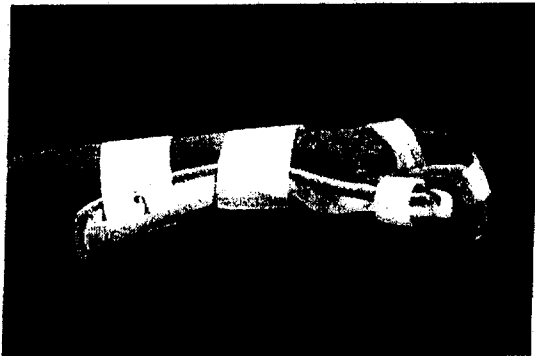
Treatment with the Ascension MCP involves surgery and then specialized rehabilitation therapy (splints and exercises). Before surgery your doctor should talk with you about your specific medical needs. You and your doctor should discuss:

- alternative treatment options
- treatment goals
- finger joint surgery
- rehabilitation therapy
- problems to look for
- any questions you have

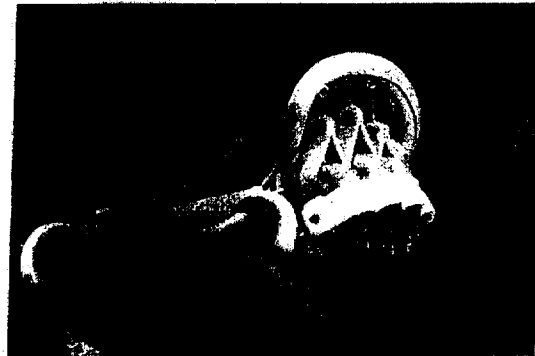
Surgery will last a few hours when the surgeon implants the Ascension MCP in your finger joint. Some soreness after surgery is normal but it should go away slowly. You may be able to move the end of your finger, but you should not try to move your operated joint for several days while it heals, according to the instructions from your surgeon.

After your surgery you will probably have:

- a bandage or a cast
- a static splint for rest or night
- a dynamic splint for day
- rehabilitation exercises



**Static splint**



**Dynamic splint**

Rehabilitation therapy may last up to 12 weeks (3 months) after surgery. You should wear the static and dynamic splints during this time. Your doctor or therapist will show you how to do the exercises. It is very important to follow their instructions carefully so you can recover from surgery with good hand function.

You will learn how to care for your hand while it heals. It is important that you:

- keep your hand clean and dry
- keep your hand raised to lessen any pain and swelling
- do not use your hand for daily activities until your doctor approves
- attend all of your appointments after surgery

Remember to call the doctor if your finger becomes:

- red
- hot
- swollen
- painful
- bent, crooked or twisted, or
- you develop a fever

## **6. GENERAL WARNINGS AND PRECAUTIONS**

- Do not use your hand for daily activities after surgery until your doctor or therapist approves. Your finger needs time to heal.
- When doing therapy exercises, move your fingers slowly and avoid pain.
- Make sure you do not twist your finger.
- Call your doctor if you see anything unusual.

## **7. ALTERNATIVE PRACTICES AND PROCEDURES**

Besides the Ascension MCP, there may be other treatments for your finger joint. Your medical condition will determine if any of these treatments are good for you. You should discuss these with your doctor.

Non-surgical treatments include:

- joint injections
- medication (such as aspirin)
- avoiding heavy lifting or use of hand and fingers
- physical therapy exercises and splints

Surgery may be necessary to help your finger joint. It is used when non-surgical treatments do not work.

Alternative surgical options are:

- surgery on your tendons and ligaments
- joint fusion surgery
- surgery with a silicone rubber spacer

Tendon and ligament surgery may improve finger motion or bent and crooked fingers. Joint fusion may reduce pain but your joint will not move. Surgery with a silicone rubber spacer may reduce pain and improve motion. However, silicone rubber spacers may not work in people who are very active and use their hands a lot.

Please be sure to discuss your situation and all your options with your doctor.